Pending Claims

Claims 1, 2, 6 and 13-16 are pending in this application. Claims 6, 15 and 16 have been withdrawn from consideration by the Examiner. Claims 1, 2, 13 and 14 are under examination in this application.

Rejoinder

Applicants reiterate their request that, upon allowance of any of the claims within the Group I claims that were elected for examination, *i.e.* claims 1, 2, 13 and 14, the method claims 6, 15 and 16, which depend therefrom, should be rejoined and examined in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products

Claim Objections

Claims 2 and 14 are objected to because they are dependent on rejected claim 1. Applicants submit that independent claim 1 is allowable for reasons presented below. Therefore, Applicants respectfully request the withdrawal of the objection to dependent claims 2 and 14.

Written Description Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1 and 13 stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of an adequate written description. In particular, the Final Office Action asserts that:

- the question is not whether one would be able to determine whether a given naturally occurring polypeptide is a variant of SEQ ID NO:1, but rather was the applicant in possession of said naturally occurring polypeptide variants of SEQ ID NO:1, such that applicants have adequately described said naturally occurring variants. (Final Office Action at pp. 3-4.)

- To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed

genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (Final Office Action at p. 5.)

- a single polypeptide comprising SEQ ID NO:1 is fully described in the form of SEQ ID NO:1, wherein the polypeptide has extracellular adhesion activity. Those sequences that are "naturally occurring" are a subset of this genus. The specification does not adequately describe this subset according to its structure so that one of skill in the art would be able to predict naturally occurring sequences...(Final Office Action at pp. 5-6.)

This rejection is respectfully traversed.

The requirements necessary to fulfill the written description requirement of 35 U.S.C. 112, first paragraph, are well established by case law.

> . . . the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed. Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)

> . . . Mention of representative compounds encompassed by generic claim language ***clearly is not required by Section 112 or any other provision of the statute***. But, where no explicit description of a generic invention is to be found in the specification...mention of representative compounds may provide an implicit description upon which to base generic claim language. *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) [emphasis added]

> . . . [I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, ***it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'*** *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) [emphasis added]

Attention is also drawn to the Patent and Trademark Office's own "Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001, which provide that :

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics[42] which provide evidence that applicant was

> in possession of the claimed invention,[43] i.e., ***complete or partial structure***, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[44] What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.[45] ***If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.***[46] [emphasis added]

Thus, the written description standard is fulfilled by both what is specifically disclosed and what is conventional or well known to one skilled in the art.

1. The specification provides an adequate written description of the claimed "variants" of SEQ ID NO:1

The subject matter encompassed by claims 1 and 13 is either disclosed by the specification or is conventional or well known to one skilled in the art.

Independent claim 1 b) recites a polypeptide that is 1) "a naturally occurring amino acid sequence" that is 2) "at least 90% identical to the amino acid sequence of SEQ ID NO:1" and having 3) "extracellular adhesion activity." The Examiner's position is based upon the theory that, although "a single polypeptide comprising SEQ ID NO:1 is fully described in the form of SEQ ID NO:1, wherein the polypeptide has extracellular adhesion activity", the subset of naturally occurring polypeptides is not adequately described "according to its structure so that one of skill in the art would be able to predict naturally occurring sequences..." (Final Office Action at pp. 5-6.) Applicants strongly disagree with this position.

Such a position ignores that the polypeptides recited in claim 1 b) ***are*** described in terms of their structure. That is, the claimed polypeptides are "***at least 90% identical to the amino acid sequence of SEQ ID NO:1***". The structure of SEQ ID NO:1 is provided in the specification, for example, at pp. 1-2 of the Sequence Listing and Figures 1A and 1B. Definitions of the phrases "percent identity" or "% identity" as well as methods for determining such identity are provided, for example, at p. 9, lines 6-20. A definition of polypeptide "variants", the types of amino acid changes and substitutions that may be made while still retaining biological or immunological activity, and computer programs well known in the art which provide guidance in identifying such variants may be

found, for example, on p. 11, line 35 to p. 12, line7. A detailed description of the chemical and structural features of SEQ ID NO:1 which contribute to the characterization of SEQ ID NO:1 and other related proteins as extracellular adhesive proteins, including a description of which amino acid residues must be conserved to retain carbohydrate binding activity is provided, for example, at p. 12, line 30 to p. 13, line 15. 90% variants of the claimed polypeptides are described, for example, at p. 14, lines 8-11.

Furthermore, claim 1, for example, recites not only that the polypeptide "variants" have extracellular adhesion activity as well as having at least 90% sequence identity to SEQ ID NO:1, but also have "***a naturally occurring amino acid sequence***." Through the process of natural selection, nature will have determined the appropriate polypeptide sequences. Given the information provided by SEQ ID NO:1 (the amino acid sequence of EXADH-1) and SEQ ID NO:3 (the polynucleotide sequence encoding EXADH-1), one of skill in the art would be able to routinely obtain "a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1, said naturally occurring amino acid sequence having extracellular adhesion activity" as recited in claim 1. For example, the identification of relevant polynucleotides could be performed by hybridization and/or PCR techniques that were well-known to those skilled in the art at the time the subject application was filed and/or described throughout the specification of the instant application. See, *e.g.*, p. 31, line 26 to p. 32, line 1; and Example VI at p. 40. Thus, one skilled in the art need not make and test vast numbers of polynucleotide sequences that are based on the amino acid sequence of SEQ ID NO:1. Instead, one skilled in the art need only screen a cDNA library or use appropriate PCR conditions to identify relevant polynucleotides/polypeptides that already exist in nature. Moreover, once a candidate polypeptide is identified, its activity can be tested, *e.g.*, using an assay such as that which is set forth in Example X on p. 42.

When provided with the detailed description as noted above, one of ordinary skill in the art "would have understood the inventor to be in possession of the claimed invention at the time of filing". That is, one of ordinary skill in the art would recognize polypeptide sequences which are variants at least 90% identical to SEQ ID NO:1. Given any naturally occurring polypeptide sequence having extracellular adhesion activity, it would be routine for one of skill in the art to recognize whether it was a

variant of SEQ ID NO:1 and to determine the % identity to SEQ ID NO:1 of the variant. Accordingly, the specification provides an adequate written description of the recited variants of SEQ ID NO:1.

2. The Examiner has attempted to apply a standard for written description different from that which is required by law

The Examiner has alleged that claims 1 and 13 do not comply with the requirements necessary to fulfill the written description requirement of 35 U.S.C. 112, first paragraph because:

- To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (Final Office Action at p. 5.)

Applicants submit that neither the written description requirement of 35 U.S.C. 112, first paragraph nor any caselaw that interprets the statute has ever set forth such a standard. Furthermore, caselaw in the area of the written description requirement of 35 U.S.C. 112, first paragraph is clear with regard to the details considered sufficient to describe a claimed genus:

> . . . Mention of representative compounds encompassed by generic claim language ***clearly is not required by Section 112 or any other provision of the statute***. But, where no explicit description of a generic invention is to be found in the specification...mention of representative compounds may provide an implicit description upon which to base generic claim language. *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) [emphasis added]

> . . . [I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, ***it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'*** *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) [emphasis added]

The specification sets forth a description of the claimed polypeptide variants using "other appropriate language" as indicated above in connection with the remarks regarding "a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1,

said naturally occurring amino acid sequence having extracellular adhesion activity". The claimed variants have been described in terms of their relationship to the chemical structure of SEQ ID NO:1 and structural requirements for biological and immunological activity at, for example, pp. 1-2 of the Sequence Listing; Figures 1A and 1B; p. 9, lines 6-20; p. 12, line 30 to p. 13, line 15; and p. 14, lines 8-11. The specification provides a means of identifying naturally occurring functional variants having 90% sequence identity with SEQ ID NO:1 and having extracellular adhesion activity at, for example, p. 11, line 35 to p. 12, line 7; p. 31, line 26 to p. 32, line 1; Example VI at p. 40; and Example X at p. 42. Applicants therefore submit that the "genus is sufficiently identified in [the instant] application by 'other appropriate language'" as stated in *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960). Furthermore, Applicants submit that "a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing" as stated in the Patent and Trademark Office's own "Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001. Accordingly, claims 1 and 13 meet the statutory requirements for written description under 35 U.S.C. 112, first paragraph.

3. Summary

The Final Office Action failed to base its written description inquiry "on whatever is now claimed." Consequently, the Action did not provide an appropriate analysis of the present claims in view of their scope. In particular, the subject matter of the claims of the instant application is defined in terms of the chemical structure of SEQ ID NO:1. The courts have stressed that structural features are important factors to consider in a written description analysis of claims to nucleic acids and proteins. In addition, the genus of polypeptides defined by the present claims is adequately described, as evidenced by specific passages of the specification as set forth above. Furthermore, the Examiner has applied to the subject application a written description standard that has no basis in the law.

For at least the above reasons it is believed that claims 1 and 13 meet the written description requirement of 35 U.S.C. § 112, first paragraph. It is therefore requested that this rejection be withdrawn.

CONCLUSION

In light of the above remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (650) 855-0555.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE CORPORATION

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